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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,254	02/03/2004	Heather Flores	P1857R1P1	2580

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EXAMINER	
WOODWARD, CHERIE MICHELLE	
ART UNIT	PAPER NUMBER
1647	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/28/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/771,254	FLORES ET AL.	
	Examiner	Art Unit	
	Cherie M. Woodward	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *2/3/2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *14 June 2007*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I (claims 1-40) in the reply filed on 3 October 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Formal Matters

2. Claims 1-40 are pending and under examination. Claims 41-72 have been cancelled by Applicant.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 14 July 2004 has been considered. A signed copy is attached hereto. It is noted that reference EP 0417563 is in German. The IDS states that an English Equivalent was attached, but it was not found in the file. In order to expedite prosecution, the Examiner has considered the German language version of EP 0417563.

Specification - Objections

4. The use of the trademarks DAIICHI (p. 64), ALFA LAVAL (p. 63), AMERSHAM PHARMACIA (p. 63), GAULIN (p. 62), MALVERN MASTERSIZERX (p. 60), PHARMACIA (p. 58), TWEEN 20 (pp. 31 and 57), CAPTISOL (pp. 27, 44, 50, 51), SIGMA (pp. 35, 50), GENTAMICIN (p. 35), ADRIAMYCIN (p. 23), and numerous trademarks on page 24, have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

5. The disclosure is objected to because of the following informalities: the trademark pharmaceutical GENTAMICIN is misspelled as GENTAMYCIN on page 35 [emphasis added]. Appropriate correction is required.

Claim Objections

6. Claims 12 and 30 are objected to because of the following informalities: the claims indicate structural similarity to Figure 1. Figure 1 appears to be identical to SEQ ID NO:1. For purposes of clarity, appropriate correction is requested.

Claim Rejections/Objections - 35 USC § 101

Statutory Type Double Patenting Rejection

7. Claims 1-40 of this application conflict with claims 1-40 of co-pending Application No. 10/495,353. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

8. Claims 1-40 of US Application 10/771,254 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 1-40 of co-pending Application 10/495,353. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Applicant is advised that should claims 1-40 be found allowable, claims 1-40 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in

wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112, First Paragraph

Scope of Enablement

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a stable lyophilized formulation of APO-2 ligand comprising about 1 mg/ml to about 20 mg/ml APO-2 ligand, about 0.2M to about 0.5M arginine salt, TRIS, and polysorbate or poloxamer, wherein said formulation has a pH of about 6 to about 9. does not reasonably provide enablement for a stable formulation of APO-2 ligand comprising any generic salt, any generic surfactant, any generic buffer, any generic preservative, and any generic sugar. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability, 5) existence of working samples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The claims recite a stable formulation of Apo-2 ligand, comprising Apo-2 ligand and about 0.2M to about 0.5M salt wherein said formulation has a pH of about 6 to about 9; wherein said salt is arginine salt; wherein the concentration of said arginine salt in the formulation is about 0.4M to about 0.5 M; wherein the arginine salt is selected from the group consisting of arginine succinate, arginine sulphate, arginine malate, arginine citrate, arginine tartrate, and arginine phosphate; wherein the arginine salt is arginine succinate; wherein the salt is sodium sulphate; wherein the Apo-2 ligand comprises crystallized protein; wherein said formulation is lyophilized; wherein the pH of said formulation is about 6.5 to about 8.5; wherein the pH of said formulation is about 7 to about 7.5; wherein the concentration of Apo-2 ligand is about 1 mg/ml to about 20 mg/ml; wherein said Apo-2 ligand comprises amino acids 114 to 281 of

FIG. 1; wherein said Apo-2 ligand is not linked or fused to an epitope tag; wherein said formulation further comprises surfactant; wherein said surfactant is a polysorbate or poloxamer; wherein the concentration of said surfactant in the formulation is about 0.005% to about 0.2%; wherein said formulation further comprises buffer; wherein said buffer is Tris buffer; wherein the pH of the formulation is about 7 to about 7.5; wherein said formulation further comprises one or more divalent metal ions; wherein said one or more divalent metal ions is zinc; further comprising a preservative; wherein said formulation is storage-stable for at least 12 months; wherein said formulation is storage-stable or at least 24 months; a stable, lyophilized formulation of Apo-2 ligand, comprising about 1 mg/ml to about 20 mg/ml Apo-2 ligand, about 0.2 M to about 0.5M arginine salt, buffer, and surfactant, wherein said formulation has a pH of about 6 to about 9; wherein said arginine salt is arginine succinate; wherein the concentration of said arginine succinate is about 0.4M to about 0.5M; wherein said buffer is Tris buffer; wherein said surfactant is a polysorbate; wherein said Apo-2 ligand comprises amino acids 114 to 281 of FIG. 1; wherein said formulation further comprises one or more divalent metal ions; a stable formulation of Apo-2 ligand, comprising about 1 mg/ml to about 20 mg/ml Apo-2 ligand, about 0.2M to about 0.5 M salt, buffer, and surfactant, wherein said Apo-2 ligand comprises crystallized protein and said formulation has a pH of about 6 to about 9; wherein said salt is sodium sulphate; wherein said buffer is Tris buffer; wherein said surfactant is polysorbate; wherein said formulation has a pH of about 7 to about 7.5; a stable formulation of Apo-2 ligand, comprising about 0.1 mg/ml to about 2 mg/ml Apo-2 ligand, sugar, and surfactant, wherein said formulation has a pH of about 6 to about 9; wherein said sugar is trehalose; wherein the concentration of the sugar in the formulation is about 1% to about 8%; wherein said formulation is lyophilized.

The nature of the invention is drawn to a stable composition comprising APO-2, also known as TRAIL, TNFSF10, and CD253 (see i.e., Information Hyperlinked Over Proteins [IHOP], TNFSF10). The state of the art discloses that control of chemical instability in protein pharmaceuticals continues to be a critical issue in developing stable formulations. Effects of pH, buffer composition, ionic strength and temperature remain the most effective methods for controlling hydrolysis and oxidation reactions. Conformational control is also important. See, i.e. Meyer et al., (Pharm Biotechnol. 2002;13:85-107, Abstract Only). The level of skill of those in the art is high due to the complexity associated with generating pharmaceutical compositions comprising recombinant proteins that are biologically active.

There are working models of a stable lyophilized formulation of APO-2 ligand comprising about 1 mg/ml to about 20 mg/ml APO-2 ligand, about 0.2M to about 0.5M arginine salt, TRIS, and polysorbate or poloxamer, wherein said formulation has a pH of about 6 to about 9. However, Applicants' claims are

excessively broad in that they recite a number of generic components, any of which may affect the biological activity of the protein in the claimed composition.

For example, claims 1, 25, and 32 recite a stable formulation comprising about 0.2M to 0.5M salt. The disclosure teaches a number of arginine salts that may be used and the art teaches the use of NaCl. However, it is unclear whether any salt may be used in the formulation without it affecting the biological activity of the protein in the claimed composition. Similarly, claims 14, 25, 32, and 37 recite generic surfactants. It is unclear whether any surfactant will work in the recited compositions. The specification does not disclose a range of equivalents for surfactants. The generic class of polysorbates and poloxamers are disclosed. However, EDTA is a chelating agent with surfactant properties. Any detergent may be used as a surfactant. The disclosure fails to provide sufficient guidance for one of ordinary skill in the art to determine whether any surfactant may be used in the composition without affecting the biological activity of the protein in the claimed composition. Claims 17, 25, and 32 recite generic buffers. A buffer may be water or it may be a complex mixture of various chemicals or proteins. For example, powdered milk is frequently used in protein (antibody) blocking buffers to reduce non-specific binding. There is insufficient guidance in the disclosure for one of ordinary skill in the art to determine whether any buffer may be used. As such, it would require undue experimentation to test a sufficient number of buffers and their effect on the biological activity of the protein in the claimed composition. Claim 22 recites generic preservatives. There is insufficient guidance in the specification to determine whether any preservative may be used without it affecting the biological activity of the protein in the claimed composition. It is unclear, for example, whether formaldehyde may be used as a preservative, and if so, whether the inclusion of formaldehyde would affect the structural integrity or biological activity of the protein in the claimed composition. Claim 37 recites generic sugars. There is insufficient guidance to determine which generic sugars will work in the claimed composition without engaging in undue experimentation. It is unclear whether any sugar will affect the tonicity or any other critical physical characteristic of the composition, thereby affecting the biological activity of the protein.

The specification fails to teach the skilled artisan how to use the claimed methods without resorting to undue experimentation to determine which generic salt, generic surfactant, generic buffer, and generic preservative will work to produce a stable formulation. Due to the large quantity of experimentation necessary to determine which generic salt, generic surfactant, generic buffer, generic preservative, and generic sugar will work to produce a stable formulation, the lack of direction/guidance presented in the specification regarding same, the absence of sufficient working examples directed to same, the complex nature of the invention, and the breadth of the claims which recite generic components

of the composition, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claim Rejections - 35 USC § 112, Second Paragraph

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1, 23, and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 23 and 24 claims recite the limitation that the formulation be "storage-stable." However, no degree of stability, range of degradation, or storage parameters are disclosed in the specification. It is unclear from the claims, as written, and the disclosure, if the breadth of the claim is intended to encompass a "shelf-life" or if they include frozen storage at, for example, -70C or –80C.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1, 7, 9-14, and 17-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Hymowitz et al., (Biochemistry, 2000 Jan 4; 39:633-640).

The claims recite a stable formulation of Apo-2 ligand, comprising Apo-2 ligand and about 0.2M to about 0.5M salt wherein said formulation has a pH of about 6 to about 9; wherein the Apo-2 ligand comprises crystallized protein; wherein the pH of said formulation is about 6.5 to about 8.5; wherein the pH of said formulation is about 7 to about 7.5; wherein the concentration of Apo-2 ligand is about 1 mg/ml to about 20 mg/ml; wherein said Apo-2 ligand comprises amino acids 114 to 281 of FIG. 1; wherein said Apo-2 ligand is not linked or fused to an epitope tag; wherein said formulation further comprises surfactant; wherein said formulation further comprises buffer; wherein said buffer is TRIS buffer; wherein the pH of the formulation is about 7 to about 7.5; wherein said formulation further comprises one or more divalent metal ions; wherein said one or more divalent metal ions is zinc.

Hymowitz et al., teach a stable formulation comprising APO2L proteins comprising amino acid residues 91-281 and 114-281 (p. 634, column 1, first full paragraph) in a composition comprising 0.1M Tris-HCL (pH 8.0), 0.2M NaCl, and 5 mM EDTA (p. 634, column 1, first full paragraph). The protein was not expressed with a histidine tag (p. 634, column 1, first full paragraph). Crystallized APO2L at a concentration of 2.6 mg/mL in 20mM Tris (pH 8.0), 10μL of 8% polyethylene glycol 2K are taught at p. 634, column 1, second paragraph. A composition comprising crystallized APO2L at a concentration of 1.7 mg/ML in 20mM Tris-HCL (pH 7.5) are taught at p. 634, column 1, second paragraph. A composition comprising APO2L (amino acids 114-281) in 20mM Tris (pH 7.5), 0.2M NaCl, 5 mM EDTA, and divalent metal ions, including Cd, Co, Zn, Ni, and Cu are taught at p. 634, column 2, last paragraph.

15. Claims 1, 9, 17-18, and 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Walczak et al., (Nature Medicine, 1999 Feb; 5(2):157-163).

The claims recite a stable formulation of Apo-2 ligand, comprising Apo-2 ligand and about 0.2M to about 0.5M salt wherein said formulation has a pH of about 6 to about 9; wherein the pH of said formulation is about 6.5 to about 8.5; wherein said formulation further comprises buffer; wherein said buffer is TRIS buffer; wherein said formulation is storage-stable for at least 12 months; wherein said formulation is storage-stable or at least 24 months.

Walczak et al., teach a stable formulation comprising recombinant LZ-huTRAIL protein in a composition comprising 0-1.0M NaCl and 20mM Tris buffer (pH 8.5) (p. 162, second column, first paragraph). Fractions containing the LZ-huTRAIL protein were dialyzed against Tris-buffered saline, divided into aliquots and frozen at –70C (p. 162, second column, first paragraph). It is well known in the art that proteins frozen at –70C are storage-stable for at least 12-24 months (see, for exemplary purposes only, Craft et al., Clin Chem, 1988 Jan;34(1):44-8, Abstract Only).

16. Claims 1, 9, 12-14, and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Ashkenazi et al., (J Clin Invest, 1999 July; 104(2):155-162).

The claims recite a stable formulation of Apo-2 ligand, comprising Apo-2 ligand and about 0.2M to about 0.5M salt wherein said formulation has a pH of about 6 to about 9; wherein the pH of said formulation is about 6.5 to about 8.5; wherein said Apo-2 ligand comprises amino acids 114 to 281 of FIG. 1; wherein said Apo-2 ligand is not linked or fused to an epitope tag; wherein said formulation

further comprises surfactant; wherein said formulation further comprises buffer; wherein said buffer is Tris buffer.

Ashkenazi et al., teach a stable formulation comprising the recombinant soluble extracellular portion of human APO2L (amino acids 114-281) that is not linked or fused to an epitope tag in a buffer containing 0.1M Tris, 0.2M NaCl, and 50mM EDTA at a pH of 8.0 (p. 159, first column, third paragraph, Methods).

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20. Claims 1 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over as being anticipated by Hymowitz et al., (Biochemistry, 2000 Jan 4; 39:633-640) in view of Page et al., (J Pharm Pharmacol, 2000 Jan;52(1):19-26, Abstract Only).

The claims recite a stable formulation of Apo-2 ligand, comprising Apo-2 ligand and about 0.2M to about 0.5M salt wherein said formulation has a pH of about 6 to about 9; wherein the formulation is lyophilized.

Hymowitz et al., teach a stable formulation comprising APO2L proteins comprising amino acid residues 91-281 and 114-281 (p. 634, column 1, first full paragraph) in a composition comprising 0.1M Tris-HCL (pH 8.0), 0.2M NaCl, and 5 mM EDTA (p. 634, column 1, first full paragraph). Hymowitz et al., do not teach a lyophilized formulation.

Page et al., teach lyophilized formulations comprising recombinant human interleukin-11 (rhIL-11). Page et al., also teach steps to prevent significant loss of recoverable biological activity during the lypholization process.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to lyophilize the APO2L variant formulation because lyophilization is a process that is commonly used to freeze-dry protein-containing compositions, particularly pharmaceuticals, in order to store them for lengthy periods of time. One would have reasonably expected success because lyophilization is an old and very common process and Page et al., teach methods to avoid loss of biological activity due to the lyophilization process.

Conclusion

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cherie M. Woodward whose telephone number is (571) 272-3329. The examiner can normally be reached on Monday - Thursday 9:00am-7:30pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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